5 510(k) Summary

Date summary prepared: 10/29/2013

DEC 20 2013

510(k) Submitter/Holder

Covidien
5920 Longbow Drive
Boulder, CO 80301

Contact

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Name of Device

Trade Name:	LigaSure™ 5 mm Maryland Jaw Sealer/Divider One-step Sealing (LF17XX series)
Catalog Numbers:	LF1723, LF1737, LF1744
Common Name:	Bipolar Electrosurgical Instrument
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, Class II, GEI).

Predicate Devices

The LigaSure™ 5 mm Maryland Jaw Sealer/Divider One-step Sealing (LF17XX series, LF1723, LF1737, LF1744) were compared to and found to be substantially equivalent to the following products of comparable type in commercial distribution:

Trade Name:	LigaSure™ 5 mm, Laparoscopic, Sealer/Divider
Device Common Name:	Bipolar Electrosurgical Instrument
Catalog Number:	LF1537
510(k) Number:	K092879 (cleared 10/16/2009)
Manufacturer:	Covidien

Trade Name:	LigaSure™ Curved, Small Jaw, Open Sealer/Divider
Device Common Name:	Bipolar Electrosurgical Instrument
Catalog Number:	LF1212A
510(k) Numbers:	K102470 (cleared 2/7/2011), K113572 (cleared 9/7/2012)
Manufacturer:	Covidien

Device Description

The LigaSure™ 5 mm Maryland Jaw Sealer/Divider One-step Sealing (LF17XX series) devices are sterile, single-use, hand-held bipolar electrosurgical instruments designed for use with the ForceTriad™ energy platform (generator) to ligate (seal) and divide (cut) vessels, tissue bundles, and lymphatics clamped between the jaws, grasping tissue, and blunt dissection during open and minimally invasive general surgical procedures using radio frequency (RF) energy. A hand actuated lever allows the user to open and close the instrument jaws without having to latch the lever, which includes a clicking mechanism that indicates to the user that the jaws are in the grasping zone, a button (switch) to activate the LigaSure™ mode by closing the handle against the button (switch) for vessel sealing, and a trigger to actuate an independent cutting blade.

Indications for Use

The LigaSure™ 5 mm, Maryland Jaw, Open / Minimally Invasive Sealer/Dividers are bipolar electrosurgical instruments intended for use with the ForceTriad™ Energy Platform in general, minimally invasive and open surgical procedures where ligation and division of vessels and lymphatics is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels and lymphatics) interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue.

Indications for use include general open and minimally invasive procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures where ligation and division of the vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

The LigaSure™ 5 mm Maryland Jaw Sealer/Divider One-step Sealing devices can be used on vessels and lymphatics up to and including 7 mm, and tissue bundles.

Technological Characteristics

The LigaSure™ 5 mm Maryland Jaw Sealer/Divider One-step Sealing (LF17XX series) has the same technological and performance characteristics as the predicates, LF1537 K092879, and LF1212A K113572. This Traditional 510(k) presents proposed modifications relating to the hand actuated lever that allows the user to open and close the instrument jaws without having to latch the lever, which includes a clicking mechanism that indicates to the user that the jaws are in the grasping zone, a button (switch) to activate the LigaSure™ mode by closing the handle against the button (switch) for vessel sealing, and a trigger to actuate an independent cutting blade.

The function of the devices remain the same as the predicates, where the new devices seal vessels and lymphatics using radio frequency (RF) energy to achieve its intended use and can mechanically divide the sealed areas or tissue with a mechanical cutting device.

Performance

Evidence of safety and effectiveness were obtained from both bench and preclinical testing. Bench testing to support the intended use of this device includes:

- Testing in accordance with IEC 60601-1
- Testing in accordance with IEC 60601-2-2
- Mechanical testing such as blade return, grasping performance, jaw temperature, jaw force, button activation force, knife deployment force, lever force, and power curve performance
- Renal and pulmonary burst pressure

Preclinical testing includes:

- Sealing and dividing vessels up to and including 7 mm
- Ability to achieve hemostasis of tissue and vessels
- Tissue bundles
- Thermal spread
- Lymphatic burst pressure
- Chronic animal study

Conclusion

The results of the testing demonstrate that the proposed devices, the LF17XX series, operated as intended and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Covidien
Mr. Donald Henton
Regulatory Affairs Manager
5920 Longbow Drive
Boulder, Colorado 80301

December 20, 2013

Re: K133338
Trade/Device Name: LigaSure™ 5 mm Maryland Jaw Sealer/Divider
One-step Sealing (LF17XX series)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 29, 2013
Received: October 30, 2013

Dear Mr. Henton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K133338

Device Name: LigaSure™ 5 mm Maryland Jaw Sealer/Divider One-step Sealing (LF17XX series)

Indications for Use:

The LigaSure™ 5 mm, Maryland Jaw, Open / Minimally Invasive Sealer/Dividers are bipolar electrosurgical instruments intended for use with the ForceTriad™ Energy Platform in general, minimally invasive and open surgical procedures where ligation and division of vessels and lymphatics is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels and lymph) interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue.

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The LigaSure 5 mm Maryland Jaw Sealer/Dividers can be used on vessels and lymphatics up to and including 7 mm, and tissue bundles.

Prescription Use (Part 21 CFR 801 Subpart D)	✓	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=13003699056
Date: 2013.12.20 08:34:14 -05'00'

for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K133338